

Applicant : Khosravi, et al.
Appl. No. : 09/427,260
Examiner : B. Pelegriño
Docket No. : 702563.4004

Remarks

Claims 29-30 and 55-62 were pending. By this Amendment, claims 55 and 59 are amended, and claim 58 is cancelled.

In the Office Action, the Examiner rejected the drawing correction for Fig. 9 that was received on November 20, 2003. The Examiner also rejected claims 29, 30, 56, and 60 under 35 U.S.C. § 112, first paragraph; rejected claims 55, 57, 59, 61, and 62 under 35 U.S.C. § 102(e); and rejected claims 29, 30, 56, 58, and 60 under 35 U.S.C. § 103(a).

Applicant respectfully requests consideration of the application and claims in view of the foregoing amendments and the following remarks.

Objections to the Drawing Correction

The Examiner rejected the drawing correction to Fig. 9 that was submitted with Applicant's previous Amendment filed November 17, 2003. The Examiner stated that the drawing "is not acceptable because it is not clear how the locking elements would work with the wing-like elements since the wing-like elements permit flexibility. Additionally, there is no description of an embodiment of this combination of features."

As to the Examiner's first objection, the manner by which the locking elements work with the wing-like elements is fully and adequately described, for example, in the specification beginning at page 18, line 19:

Preferably, the teeth 24 on the inner longitudinal edge 20 engage a set of the openings 32 in the sheet 12, thereby substantially locking the stent 10 in its enlarged condition. Thus, the teeth 24 allow the stent 10 to be ratcheted to a

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number of enlarged conditions as long as the inner and outer longitudinal sections 26, 28 overlap and allow the teeth 24 to engage corresponding openings 32, as will be appreciated by those skilled in the art.

As explained below, although this description is presented in relation to the stent embodiments shown in Figures 1A and 1B, the description applies equally to the alternative stent embodiments described elsewhere in the specification, including those shown in Figures 9 and 10A-B. In those figures, just as in Figs. 1A-B, the locking teeth 24 engage the openings formed in the sheet by the stretchable elements 730. The fact that the “wing-like elements permit flexibility” does not change the manner by which the locking elements “work,” insofar as the stretchable elements 30 shown in Figures 1A-B also permit flexibility. Moreover, the Examiner has not provided a reason why this “flexibility” should have any bearing on the manner by which the locking elements “work.”

The Examiner's second objection is that “there is no description of an embodiment of this combination of features.” This objection is addressed in full in the remarks below concerning the § 112 rejection.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

In the Office Action, the Examiner rejected claims 29, 30, 56, and 60 under 35 U.S.C. § 112, first paragraph, “because the specification, while being enabling for a coiled sheet stent with stretchable or wing-like elements or a stent with locking elements, does not reasonably provide enablement for the combination of features.” Applicant respectfully disagrees. The Examiner states further that “variations or alternative embodiments are

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only permitted to be claimed where the species for which coverage is desired are taken from one true genus." (Citation omitted). Applicant respectfully submits that this is exactly what Applicant has done.

Figures 1A and 1B show a coiled-sheet stent 10 that is formed from a substantially flat sheet 12 having first and second ends 14, 16 defining a longitudinal axis 18 therebetween. (Spec., pg. 13, ll. 17-19). "The sheet 12 also includes first and second longitudinal edges 20, 22, the first edge having a plurality of fingers or teeth 24 extending therefrom substantially perpendicular to the longitudinal axis 18." (Spec. pg. 13, line 20 to pg. 14, line 2).

The sheet 12 also includes a plurality of stretchable elements 30 formed therein, thereby defining a multi-cellular structure capable of expanding and/or contracting in a direction substantially perpendicular to the longitudinal axis 18. Preferably, the stretchable elements 30 define a lattice-like structure providing a plurality of openings 32 for receiving the teeth 24, as described further below. The stretchable elements 30 may be elastically deformable, i.e., biased to assume a first shape but temporarily deformable from that first shape, and/or may be plastically deformable, i.e., assuming any shape to which the stretchable elements 30 are deformed.

(Spec., pg. 14, ll. 3-13).

This is a clear, explicit, and generic description of a stent comprising a flat sheet 12, upon a longitudinal edge of which are formed locking teeth 24, and within a body of which are formed a plurality of stretchable elements 30.

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As the specification further states:

The stretchable elements included in the coiled-sheet stents may take on a number of different forms. Generally, a plurality of stretchable elements are provided in a predetermined arrangement, such as the longitudinal or radial configurations described above, although a variety of arrangements providing a desired recoil or flexibility characteristic may be provided. Thus, each stretchable element generally comprises an individual cell, thereby providing a multi-cellular structure when the individual cells are duplicated in a predetermined pattern, **as in the preferred embodiments described below.**

(Spec., pg. 22, line 21 to page 22, line 9) (Emphasis added). If this portion of the specification is to have any meaning, it must mean at least that there are a number of embodiments of the "stretchable elements" feature "described below", and that those are able to be substituted into the generically described stent shown in Figs. 1A-B. Several of the forms of these stretchable elements are shown in the figures, including the "wing-like elements" shown in Figures 9, 10A, and 10B, (See Spec., pg. 28, l. 6 to pg. 29, l. 8).

Thus, contrary to the Examiner's objection, the specification **explicitly** states that the features of the rejected claims may be combined in **alternative embodiments**. Included amongst those alternative embodiments are stents having a coiled sheet 12 and locking teeth 24 as illustrated, for example, in Figs. 1A-B, but in which the "stretchable elements" are those having wing-like elements as illustrated in Figs. 9 and 10A-B.

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Claim Rejections – 35 U.S.C. § 102(e)

In the Office Action, the Examiner rejected claims 55, 57, 59, 61, and 62 under 35 U.S.C. § 102(e) over U.S. Patent No. 5,800,520 ("the Fogarty et al. patent" or "the '520 patent"). In response, Applicant has amended claims 55 and 59 to recite that each of the wing-like elements "comprises first and second members having undulations," a feature that is neither taught nor suggested in the Fogarty patent.

Accordingly, Applicant submits that the rejection of these claims under § 102(e) has been overcome, and requests that the rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 103

In the Office Action, the Examiner rejected claim 58 for obviousness over the Fogarty patent in view of U.S. Patent No. 5,895,406 ("the Gray et al. patent" or "the '406 patent"). Applicant has cancelled claim 58, thereby obviating this rejection.

The Examiner also rejected claims 29, 30, 56 and 60 over the Fogarty patent in view of U.S. Patent No. 5,441,515 ("the Khosravi et al. patent" or "the '515 patent"). As to the rejection of claims 56 and 60, this rejection is overcome by the amendment to claims 55 and 59 to recite that the wing-like elements each comprise "first and second members having undulations," a feature neither taught nor suggested in either the Fogarty patent or the Khosravi patent. The rejections of these claims should therefore be withdrawn on this basis.

As to the rejection of claims 29 and 30, and as to all of the Examiner's stated rejections based upon combinations of the Fogarty, Gray, and/or Khosravi patents,

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Applicant once again submits that the Examiner has failed to identify any teaching, either from the references or elsewhere, as to why a person of skill in the art would be motivated to combine the disparate teachings of these three patents in the manner done by the Examiner. In his response to Applicant's previous arguments on this issue, the Examiner stated his recognition that obviousness can be established by combining or modifying the teachings of the prior art only where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Examiner stated that, in this case, "the features of either Gray or Khosravi can be said to improve the stent of Fogarty." This is, quite simply, an inadequate finding upon which to reject the present claims.

To begin with, it matters not whether the features described in a first reference "can be said to improve" a device shown in a second reference. There would be very few patents granted if this were the standard for proving a prima facie case of obviousness. Indeed, this rationale represents pure hindsight reconstruction, which is improper. Sensonic, Inc. v. Aerosonic Corp., 81 F.3d 1350, 1358 (Fed. Cir. 1998). Instead, the Examiner must show why someone of skill in the art would be motivated to combine the **specific** teachings of the cited references in the manner relied upon. Here, that means that the Examiner must show some teaching that would have motivated a person of skill in the art to combine the wavy longitudinal bands described in the Gray patent, with the locking teeth described in the Khosravi patent, with the coiled-sheet stent described in the Fogarty patent, and to do so without regard to any of the contrary teachings contained in those references. It is not enough to simply pick and choose these features from the

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reference disclosures and state that they represent desirable “improvements” and that, therefore, one would have been motivated to make the combination. See, e.g., WMS Gaming, Inc. v. International Game Technology, 184 F.3d 1339, 1359 (Fed. Cir. 1999). Against this standard, the Examiner has failed to demonstrate a prima facie case of obviousness, because such a showing cannot be made on the basis of these varied references. There simply is no teaching available, either from the references or elsewhere, that would supply the motivation to make the combination relied upon by the Examiner. Once again, Applicant respectfully requests withdrawal of the claim rejections made in reliance on combinations of these references.

In addition, the Gray patent plainly teaches away from any combination of its teachings with stents like those described in the Fogarty patent. In particular, the “Background” section of the Gray patent states that stents having “cylindrical elements connected by flexible members” (like those shown in Fig. 1(a) of the Gray patent) have a disadvantage because the edges protrude when the stent is flexed around a curve. (Gray, col. 1, ll. 30-40, Fig. 1(a)). This “disadvantageous” structure is exactly what is described in the Fogarty patent, which describes stents including cylindrical band members 11 and bridge elements 13. (See, e.g., col. 9, ll. 1-10). The stents illustrated in Figures 7 through 10 of the Fogarty patent would have these same “protruding edges” when the stent is flexed around a curve. Thus, the Gray patent teaches away from any combination with structures such as those shown in the Fogarty patent. This is yet another reason why the combination would not have been made by a person of skill in the art, and why there can be no prima facie case of obviousness based upon any combination of these patents.

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The mere fact that several of the elements of Applicant's claims may be found in the three cited references is simply not enough to support a *prima facie* case of obviousness. See In re Rouffet, 149 F.3d 1350, 1358 (Fed. Cir. 1998). Indeed, the only support for making the combination is to use Applicant's claims as a template, which is improper. Sensonics, 81 F.3d at 1570. For these reasons, Applicant respectfully requests reconsideration of the rejections made in the present Office Action, and allowance of claims 29-30, 55-57, and 59-62.

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CONCLUSION

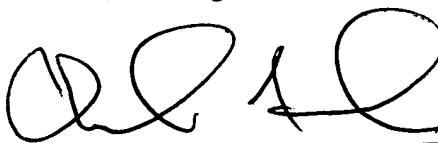
In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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